

COMMENT TO CASAC ON THE HEALTH RISK ASSESSMENT: SEPTEMBER 11, 2012

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During the EPA presentation at the meeting, Dr. Pekar stated that confidence intervals for the epidemiological parameters were not used in assessing the variability of the mortality reduction due to changes in the ozone level. Another EPA speaker stated that the hierarchical Bayesian approach was not used. I query why this is the case. The hierarchical Bayesian approach is now well established in many papers including Bell et al. (2004), Bell et al. (2006) and Smith et al. (2009). It is not difficult to apply the posterior distributions derived from this approach to the problem of risk reduction. Bayesian probability intervals may be derived from the posterior distributions, and in this context, are equivalent to frequentist confidence intervals for all practical purposes.

A caveat with the use of Bayesian estimates is that different prior distributions do yield different results. Smith et al. (2009) consider three different priors: a “national prior” (assuming a common prior distribution of city-specific ozone-mortality coefficients), a “regional prior” (where the prior mean at each city is dependent on region) and a prior distribution defined by spatial statistics. The posterior distributions from these three priors are substantially different and this uncertainty needs to be acknowledged in any Bayesian analysis. The distinction between the national and regional prior results is acknowledged on page 7-37 of the draft REA, but does not seem to have been incorporated into the analyses.

The paper of Smith et al. (2009) was not included among the studies listed in Table 7-4 (page 7-25 and subsequently) though it apparently satisfies all the criteria listed for inclusion in that table. Tables 1 and 6 of the cited paper include coefficients for a variety of linear and piecewise-linear concentration-response functions (the tables in that paper give the nationally averaged coefficients and root mean square errors but the individual-city coefficients, from which those tables were derived, are available from the author on request).

Regarding the comparison between quadratic rollback functions and the proposed HDDM approach, while I acknowledge and agree with many of the criticisms of the quadratic rollback approach, and can understand the potential advantages of switching to a model-based HDDM approach, I would not recommend abandoning the quadratic rollback approach just yet. The main advantage of the rollback approach is transparency: the user can easily test the sensitivity of the risk assessment to parameters involved in the rollback function. I do not believe the HDDM approach should be used for rulemaking until it is thoroughly validated, and I do not see how that will be possible within the timeframe available for completing this assessment.

In any case, regardless of whether the rollback approach or a model-based approach is used, the risk assessment should incorporate the uncertainty in ozone reductions as a result of a possible new standard.

I would also like to make some comments about the epidemiological models used for the risk assessment. In my opinion, the time period used for constructing the models should be the same as that

used for the risk assessment itself. There are a number of reasons for this, among them the possibility that the ozone-health endpoint coefficients could change over time, possibly as a result of the changing composition of air pollution. The most up to date dataset that is fully public is NMMAPS, but that ended in 2000, so it now looks rather out of date. My understanding is that more up to date datasets have been derived, but have not been released to the public. I think this should be an Agency decision: EPA should decide upon the time period used for the assessment based on the availability, quality and relevance of both the air pollution and the health endpoint data, but having made that decision, it should publish all the relevant data so that the results are fully verifiable.

Ultimately, I believe the risk assessment community for air pollution will take an ensemble approach to uncertainty, similar to what has already become very popular in the scientific community related to climate change. The idea is to vary all the unknowns – including epidemiological parameters, changes in ozone concentrations, and of course also taking into account the random distribution of mortality or morbidity itself – to generate a Monte Carlo sample from the health endpoint of interest. This would not be an overwhelming task computationally – I have informally implemented such an approach using the NMMAPS data and an analytic rollback function and it is not very expensive to run. This would not resolve all the uncertainties involved in risk assessment, but it would at least allow us to incorporate the uncertainties that we know and understand.

References

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Smith, R.L., Xu, B. and Switzer, P. (2009), Reassessing the relationship between ozone and short-term mortality in U.S. urban communities. *Inhalation Toxicology*, 2009; 29(S2): 37–61